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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,255	03/23/2000	NATALYA RAPOPORT	T5986PCT.US	3065

22477 7590 04/25/2002

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# BEST AVAILABLE COPY

## Office Action Summary

Application No.

09/509255

Applicant(s)

RAPPORT

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- ☒ Responsive to communication(s) filed on 1/14/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1-62 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-3, 5-11, 13-19, 21-26, 28-31, 40, 42-46, 48-51, 53-57, 59-62 is/are rejected.
- ☒ Claim(s) 4, 12, 20, 27, 32-39, 41, 47, 52, 58 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

### Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
  - ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received

In this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Refereed (s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11, 13-15, 46, 48, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Alakhov et al.

Alakhov et al (abstract, column 2 line 10, column 3, lines 3, lines 24 and 37) teach micelles comprising poloxamers to deliver an anti-neoplastic such as doxorubicin<sup>ci</sup> 10, 63-64.

Claims 9-11, 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Michaels.

Michaels (abstract), column 3 lined 59-60 teaches micelles comprising poloxamers to deliver a pharmaceutical agent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-11, 13-19, 21-26, 28-31, 40, 42-46, 48-51, 53-57, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alakhov et al in view of Unger et al '430.

Alakhov et al is discussed above.

Unger '430 teaches Delivery of Bioactive agents from vesicular species by rupturing<sup>with</sup> them ultrasound (column 28 lines 32-36). Micelles are specified (abstract).

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It would be obvious to one of ordinary skill to deliver the active agents in the micelles of Alakhov et al by rupturing the micelles with ultrasound in view of Unger '430.

As to the claimed enhancement of up take and reduction of side effects, one of ordinary skill would <sup>would insure as</sup> Recognize such benefits a matter of course from the local nature of the ultrasound application.

As to the claimed ruboxyl, it is argued that it is equivalent to doxorubicin. NO criticality has been shown. In re Boesch<sup>h</sup> 205 USPQ 215 (CCPA 1980).

Claims 1-3, 5-11, 13-19, 21-26, 28-31, 40, 42-46, 48-51, 53-57, 59-62 are rejected.

Claims 4, 12, 20, 27, 32-39, 41, 47, 52, 58 are objected to as dependent on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Webman/LR

April 11, 2002

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500